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EXAMINER

RAPILLO, KRISTINE K

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3626

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/788,900	Applicant(s) COSENTINO ET AL.	
	Examiner KRISTINE K. RAPILLO	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 31-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 31-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/14/2005; 11/21/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant elected the invention of Group I (claims 1 – 10 and 31 – 41) based on the suggested restriction requirement received 10/30/2007. Claims 1—10 and 31 – 41 are presented for examination.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because the following reference characters have been used to designate more than one step or function.

- 104 (Figure 1) and 1606 (Figure 16) both designate "Server"
- 106 (Figure 1) and 1610 (Figure 16) both designate "Datastore"
- 108 (Figure 1) and 1604 (Figure 16) both designate "Network"
- 110 (Figure 1) and 1602 (Figure 16) both designate "Device"
- 112 (Figure 1) and 1600 (Figure 16) both designate "User"
- 210 (Figure 2) and 300 (Figure 3) were used to designate "Exception Monitoring Screen"
- 1302 (Figure 13) and 1400 (Figure 14) were used to designate "Max Allowed Wt"
- 1304 (Figure 13) and 1402 (Figure 14) were used to designate "Trigger lbs"
- 1306 (Figure 13) and 1404 (Figure 14) were used to designate "Min Wt"
- 1312 (Figure 13) and 1410 (Figure 14) were used to designate "Wt Graph"

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figure 2 – 212; Figure 10 – 1002; Figure 13 – 1314; and, Figure 17 - 1706.

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3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character 1704 (Figure 17) has been used to designate both "Decision Trees" (paragraphs [0091] and [0092] of specification) and "2-Dimensional Matrix" (paragraph [0094] of specification).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1—2, 4, 6 – 7, 9 – 10, 31 – 32, 35 – 39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Iliff (U.S. Patent Number 5,594,638).

In regard to claim 1, Iliff teaches a system for determining whether a person should have health care professional attention and for providing clinical notes to the caregiver, the system comprising:

- a monitoring device having a microprocessor operably coupled to a memory unit (column 7, line 63), an input device (column 4, lines 39 – 49), an output device (column 4, lines 39 – 49), and a communication device (column 7, lines 49 – 62), the memory unit being programmed with a set of instructions for posing questions to the person via the output device (column 6, lines 34 – 44), receiving answers from the person via the input device (column 6, lines 34 – 37), and transmitting the answers to a remote computer via the communication device (column 6, lines 34 – 37). The Examiner interprets a monitoring device to be any type of device (i.e. computer, blood pressure monitor) which can monitor a patient's health.
- the remote computer (column 4, lines 39 – 49) being programmed (column 2, lines 41 - 48) to determine whether the person should have health care professional attention based at least in part upon the answers entered into the input device (column 35, lines 33 – 42) ; and

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- automatically generate a clinical note based upon the answers transmitted to the remote computer (column 28, lines 19 – 34).

In regard to claim 2, Iliff teaches the system of claim 1, further comprising:

- a datastore accessible by the remote computer (column 7, lines 60 – 62);
- wherein the datastore stores clinical text associated with the questions posed to the person via the monitoring device (column 8, lines 27 – 28); and
- wherein the remote computer is programmed to generate the clinical note based at least in part upon the clinical text stored in the datastore (column 28, lines 19 – 34).

In regard to claim 4, Iliff teaches the system of claim 1, wherein the clinical note comprises verbiage presenting symptoms reported by the person via the input device (column 8, lines 27 – 28).

In regard to claim 6, Iliff teaches the system of claim 1, wherein the remote computer is further programmed to present a user interface that permits viewing of the clinical note and also permits viewing of a populace of persons identified as potentially needing attention by a health care professional (column 6, lines 38 – 44).

In regard to claim 7, Iliff teaches the system of claim 1, wherein the clinical note is communicated to a health care professional (column 28, lines 27 - 29).

In regard to claim 9, Iliff teaches the system of claim 1, wherein the remote computer is further programmed to present questions to be posed to the person using the monitoring device, the questions being used to verify the determination that the person should have health care professional attention (column 2, lines 41 – 48 and column 35, lines 33 – 42).

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In regard to claim 10, Iliff teaches the system of claim 1, wherein the remote computer is further programmed to provide a user interface (column 6, lines 38 – 44) permitting selection of a disease state for monitoring by the monitoring device (column 50, lines 53 – 58).

In regard to claim 31, Iliff teaches a system for determining whether a person should have health care professional attention, the system comprising:

- a monitoring device having a microprocessor operably coupled to a memory unit (column 7, line 63), an input device (column 4, lines 39 – 49), an output device (column 4, lines 39 – 49), and a communication device (column 7, lines 49 – 62), the memory unit being programmed with a set of instructions for posing questions to the person via the output device (column 6, lines 34 – 44), receiving answers from the person via the input device (column 6, lines 34 – 37), and transmitting the answers to a remote computer via the communication device (column 6, lines 34 – 37);
- the remote computer (column 4, lines 39 – 49) being programmed to determine whether the person should have health care professional attention based at least in part upon the answers entered into the input device (column 35, lines 33 – 42); and
- permit entry (column 21, lines 13 – 26), storage (column 7, lines 49 – 62), and presentation of intervention data (column 55, lines 33 – 47).

In regard to claim 32, Iliff teaches the system of claim 31, wherein the intervention data includes data regarding a symptom to be counteracted and an action to be undertaken to counteract the symptom (column 55, lines 33 – 47).

In regard to claim 35, Iliff teaches the system of claim 31, wherein the remote computer is further programmed to present a user interface that permits viewing of a populace of persons identified as potentially needing attention by a health care professional (column 6, lines 38 - 44).

In regard to claim 36, Iliff teaches the system of claim 31,

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- wherein the remote computer system is further programmed to present an operator with a set of questions, so that the operator may pose the questions to the person using the monitoring device, in response to the person having been identified as potentially needing attention by a health care professional (column 35, lines 11 - 42);
- wherein the set of questions are designed to permit a conclusion to be drawn regarding a diagnosis of a symptom reported by the person using the device (column 40, lines 41 – 56); and
- wherein the set of questions are designed to permit a conclusion to be drawn regarding selection of an intervention appropriate for the diagnosis (column 40, lines 41 – 56 and column 41, lines 46 – 62).

In regard to claim 37, Iliff teaches the system of claim 36, wherein the remote computer is further programmed to arrive at a preliminary diagnosis and preliminary intervention as a function of the person's answers to the questions posed by the operator (column 39, line 7 through column 42, line 9).

In regard to claim 38, Iliff teaches the system of claim 37, wherein the remote computer is further programmed to generate a clinical note based upon the preliminary diagnosis and the preliminary intervention (column 28, lines 19 – 34).

In regard to claim 39, Iliff teaches the system of claim 36, wherein the set of questions is chosen based upon the answers transmitted to the remote computer by the monitoring device (column 39, line 7 through column 42, line 9).

In regard to claim 41, Iliff teaches the system of claim 31, wherein intervention data is automatically entered into the remote computer, in response to the remote computer determining that the person should have health care professional attention (column 35, lines 33 – 42).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 5, 8, 33 – 34, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff, in view of Brown (U.S. Publication Number 2003/0069753 A1).

In regard to claim 3, Iliff teaches the system of claim 2, wherein the datastore also stores a symptom identifier associated with each of the questions posed to the person via the monitoring device (column 7, line 63 through column 8, line 42), wherein the remote computer is programmed to select a grammatical rule for construction of the clinical note based upon the symptom identifier (column 8, lines 27 – 28).

The Examiner interprets a grammatical rule to be a system which inserts canned or pre-programmed text into a report or summary so as to link symptoms identified by the patient.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a grammatical rule for construction of the clinical note based upon the symptom identifier as taught by Iliff with the motivation of providing a summary of the questions or symptom identifier step using appropriate medical terminology (column 28, lines 16 – 34).

In regard to claim 5, Iliff teaches the system of claim 1 wherein the remote computer is further programmed to generate a clinical note based upon the measurement transmitted to the remote computer (column 28, lines 19 – 34).

Iliff fails to teach a system wherein: the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor and the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and to transmit the measurement to the remote computer; and the remote computer is further

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programmed to generate a clinical note based upon the measurement transmitted to the remote computer.

Brown teaches a system wherein: the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor (paragraph [0090]) and the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and to transmit the measurement to the remote computer (paragraph [0090]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a system wherein the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor and the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and to transmit the measurement to the remote computer as taught by Brown, within the system of Iliff, with the motivation of accurately monitoring individuals using a networked system (paragraph [0040]) which would provide results to a health care provider. The health care provider can then advise the patient to seek immediate medical attention as taught by Iliff (column 35, lines 33 – 42).

In regard to claim 8, Iliff teaches the system of claim 7. Iliff fails to explicitly teach a system wherein the communication occurs via e-mail.

Brown teaches a system wherein the communication occurs via e-mail (appendix: page 105).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a system wherein the communication occurs via e-mail as taught by Brown, within the system of Iliff, with the motivation of allowing a health care provider and patient the ability to communicate with one another (paragraph [0041]).

In regard to claim 33, Iliff teaches the system of claim 32. Iliff fails to teach a system wherein the intervention data further includes the date upon which the intervention data was entered into the remote computer system.

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Brown teaches a system wherein the intervention data further includes the date upon which the intervention data was entered into the remote computer system (appendix: Figure 2, page 23).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a system wherein the intervention data further includes the date upon which the intervention data was entered into the remote computer system as taught by Brown, within the system of Iliff, with the motivation of enabling a health care provider the ability to track any medical advice or treatments recommended, and to determine if the results are acceptable or a new course of treatment should be prescribed (paragraph [0038] and [0149]).

In regard to claim 34, Iliff teaches the system of claim 33. Iliff fails to teach a system wherein the intervention data further includes an indication of whether or not the action has counteracted the symptom.

Brown teaches a system wherein the intervention data further includes an indication of whether or not the action has counteracted the symptom (appendix: Figure 6, page 27).

The motivation to combine the teachings of Iliff and Brown is discussed in the rejection of claim 33, and incorporated herein.

In regard to claim 40, Iliff teaches the system of claim 36. Iliff fails to teach a system wherein the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor; the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and to transmit the measurement to the remote computer; and the remote computer is further programmed to choose the set of questions based upon the answers transmitted to the remote computer and the measurement taken by the biometric measurement unit.

Brown teaches a system wherein the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor; the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and

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to transmit the measurement to the remote computer (paragraph [0090]); and the remote computer is further programmed to choose the set of questions based upon the answers transmitted to the remote computer and the measurement taken by the biometric measurement unit (paragraph [0041]).

The motivation to combine the teachings of Iliff and Brown is discussed in the rejection of claim 5, and incorporated herein.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sun et al. (U.S. Publication Number 2002/0022973 A1) discloses a medical information management system and patient interface appliance. Sun et al. teaches the use of portable devices to receive, store, and manage medical information using a central database. Riff et al. (U.S. Publication Number 2002/0082480 A1) teaches a system and method for computer enabled network patient management of medical devices used in chronic disease management.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTINE K. RAPILLO whose telephone number is (571)270-3325. The examiner can normally be reached on Monday to Thursday 6:30 am to 4 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KKR

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626